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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,363	07/01/2003	John R. Desjarlais	067461-5105-US01	4995

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

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10/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/611,363

Applicant(s)

DESJARLAIS ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,11-14,16,19,23,26 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,11-14,16,19,23,26 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of Application, Amendments and/or Claims

The amendment filed 17 July 2007 has been entered in full. Claims 3, 6-10, 15, 17, 18, 20-22, 24, 25, 27-29 were canceled. Claim 33 is withdrawn.

Applicant traversed the withdrawal of claim 31 in the previous Office Action (06 June 2007; page 2). Applicant's arguments were considered but not found persuasive because it was unclear what the claim limitation, "and fusion of said variant protein to another entity" encompassed. In view of the instant amendment (deletion of the limitation, "and fusion of said variant protein to another entity"), claim 31 has been rejoined with Group I.

Claims 1, 2, 4, 5, 11-14, 16, 19, 23, 26, 30-32 are under examination.

The Examiner acknowledges the Letter to the Examiner and Statement of Relatedness (In view of *McKesson Information Solutions v. Bridge Medical*; Fed. Cir. 2007) submitted 25 September 2007.

Withdrawn Objections And/Or Rejections

The rejection to claims 1-26, 29, 30 and 32 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 3-8 of the previous Office Action (06 June 2007), is *withdrawn* in view of the amendment (17 July 2007).

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The objection to claims 1, 11, 12, 16, 17, 21, 22 and 25, as set forth at page 8 of the previous Office Action (06 June 2007), is *withdrawn* in view of the amendment (17 July 2007).

NEW CLAIM REJECTIONS/OBJECTIONS

Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 11-14, 16, 19, 23, 26, 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "a variant RANKL protein comprising an amino acid modification at C221S and I247E and at least one further amino acid modification selected from the group consisting of **H225A**" (claim 1, 2, 11, 12, 16).

Applicant's amendment, filed 17 July 2007, asserts that no new matter has been added. Applicant does not provide sufficient direction for the written description for the above-mentioned "limitations" and the Examiner cannot locate the wording or

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connotation of the instant claims. The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 11-14, 16, 19, 23, 26, 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 appears to require a comma (",") between H225A and H225T in line 4. If this punctuation was not omitted, the claim is confusing because it appears to be directed to two mutations at the same position at the same time. See also claim 16.

Claim 2 is confusing in reciting "group consisting of: a) (H225A, H225T, ...or H225R) and (E269R, E269T,...or E269K), (H225A, H225T,...or H225R); and (E226Q, E226D, E226R)." As amended there is only an "a)" group and no other additional group. The mutations at position 225 are listed twice. The mutations at position 226

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are not in the alternative but appear to be directed to three mutations at the same position at the same time. Clarification is requested.

Claim 11 is confusing in listing groups a), b), c), d) and f). There is no group e). Clarification is requested.

Claim 12 is confusing in reciting "E269R, E269T, E269Q and E269K." This appears to require four mutations at the same position at the same time. Clarification is requested. Claim 13 is similarly confusing.

Furthermore, it is unclear if the instant variant RANKL proteins comprise triple, quadruple or more point mutations.

The metes and bounds of claims 1, 2, 4, 5, 11-14, 16, 19, 23, 26, 30 and 32 cannot be determined.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 11-14, 16, 19, 23, 26, 30-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23, 37, 42 of copending Application No. 10/338,785. The instant claims are drawn to a RANKL protein comprising an amino acid modification at C221S and I247E and at least one further amino acid modification at positions including H225T, H225N, H225E, H225R, R223Q, E226Q, E226D, E226R, Q237E, Q237K, said variant RANKL protein wherein the protein is modified by glycosylation or pegylation, and a pharmaceutical composition comprising said variant RANKL protein and a pharmaceutical carrier. The claims 21-23, 37, 42 of copending Application No. 10/338,785 are drawn to a variant RANKL protein comprising amino acid substitutions at C221S and I247E and at least one set of substitutions selected from the group consisting of H225T, H225N, H225E, H225R, R223Q, E226Q, E226D, E226R, Q237E, Q237K, said variant RANKL protein wherein the protein is modified by glycosylation or pegylation, and a composition comprising said variant RANKL protein and a carrier. Although the claims of copending Application No. 10/338,785 and the instant application are not identical they are not patentably distinct from each other. Both sets of claims

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teach the same double point mutation in RANKL (i.e. amino acid substitutions at C221S and I247E). The sets of claims differ because they teach other mutations that can be made in the variant double point mutation RANKL protein. However, it would have been obvious to make those amino acid modifications as recited in copending Application No. 10/338,785 because both sets of claims encompass amino acid modifications, wherein amino acid residues at similar positions are replaced with similar amino acid residues in the variant double point mutation RANKL protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



RMD
10/8/07



MARIANNE P. ALLEN
PRIMARY EXAMINER

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